

REMARKS

I. INTRODUCTION

Claims 1, 14, 20 and 26 have been amended. Claim 27 has been added. Claims 6, 9 and 16 have been previously canceled. No new matter has been added. Thus, claims 1 - 5, 7, 8, 10 - 15 and 17 - 27 are now pending in the present application. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

II. THE 35 U.S.C. § 112 REJECTION SHOULD BE WITHDRAWN

Claims 1 - 5, 7, 8, 10 - 15 and 17 - 26 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. *10/24/08 Office Action*, p. 5. The Examiner states that a negative limitation must be explicitly set forth in the Specification and that the limitation of a “non-annular electrode” is not supported in the disclosure of the invention. *Id.*

It is respectfully submitted that claims 1, 14 and 20 have been amended such that a “*non-annular*” electrode is no longer recited. Thus, it is respectfully submitted that claims 1, 14 and 20 are in condition for allowance. Because claims 2 – 5, 8, 10 – 13, 15, 17 – 19, 21 – 26 and newly added claim 27 depend from and include all of the limitations of one of the independent claims 1, 14 and 20, it is respectfully submitted that these claims are also allowable.

III. THE 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) REJECTION SHOULD BE WITHDRAWN

Claims 1-5, 7, 8, 10, 12-15 and 17-26 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Publication Appln. No. 2003/0097167 to Friedman (“Friedman”) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Friedman in view of U.S. Patent No. 6,855,116 to Atlee III (“Atlee”), or in view of U.S. Patent No. 6,266,549 to Melnikoff et al. (“Melnikoff”) or in view of U.S. 7,212,867 to Van Venrooij et al. (“Venrooij”). *10/24/08 Office Action*, p. 6.

Claim 1 recites a medical apparatus comprising “a flexible probe for accessing a patient’s esophagus via the mouth, the probe, when in an operative position, extending from a proximal end which remains outside the patient to a distal end within the esophagus” in combination with “an echocardiography transducer coupled to the distal end of the probe so that, when the probe is in the operative position, the echocardiography transducer is at a predetermined location within the esophagus relative to the heart to perform a transesophageal echocardiography procedure” and “*the sheath including an electrode that is embedded in the sheath so that the electrode is covered by a portion of the sheath*, when in an operative position, the electrode delivers a cardioversion current to the heart.” Support for the amended claim language may be found at p. 4, ¶ [0041] of the Published Specification.

In contrast, Friedman discloses an esophageal probe with electrode rings that are clamped over a silicone sheet assembly wrapped around a distal end of the probe such that no portion of the silicone sheet assembly covers the electrode rings. Specifically, Friedman describes the distal portion 14 of an elongated flexible member 10 as being wrapped with a silicone sheet subassembly 30 that contains electrical contacts 25 and conductors 24 to each contact 25. *Friedman*, p. 3, ¶ [0032]. Clamped over the electrical contacts 25 of the silicone sheet subassembly 30 are electrode rings 26. *Id.* at ¶ [0031] and [0032]. As the electrode rings 26 are clamped over the silicone sheet subassembly 30, it is respectfully submitted that the electrode rings 26 are not covered by any portion of the silicone sheet subassembly.

The Examiner asserts that the electrical contacts 25 are also functional as electrodes. *10/24/08 Office Action*, p. 7. It is respectfully submitted that the electrical contacts 25 cannot and do not act as electrodes as they are always covered by the electrode rings 26 and act only to expose an end of the conductor 24 such that they may contact the electrode rings 26. *Id.* at ¶ [0033]; *see* Fig. 2D. However, even if the electrical contacts 25 could be considered an electrode, it is respectfully submitted that Friedman does not show or suggest that the electrical contacts 25 are covered by any portion of the silicone sheet subassembly 30. Indeed, Fig. 2D shows the electrical contacts 25 extending outwardly of the silicone sheet subassembly 30 to

contact the electrode rings 26. Thus, it is respectfully submitted that the electrical contacts 25 are not covered by any portion of the sheet subassembly 30.

Accordingly, it is respectfully submitted that Friedman does not show or suggest “*the sheath including an electrode that is embedded in the sheath so that the electrode is covered by a portion of the sheath,*” as recited in claim 1. Therefore, it is respectfully submitted that claim 1 is not anticipated by Friedman.

In the alternative, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine the device of Friedman with the device of Atlee, Melnikoff or Van Venrooij. *10/24/08 Office Action*, p. 7. It is respectfully submitted that neither Atlee nor Melnikoff nor Van Venrooij cure the deficiency of Friedman, as discussed above.

In particular, Atlee discloses various types of electrodes mounted onto an outer wall of a carrier member such that no portion of the carrier member covers the electrodes. In a first embodiment, Atlee teaches bipolar electrodes 48, 50 mounted onto a carrier member 22. *Atlee*, col. 5, ll. 63 – 67. Bipolar electrodes 48, 50 and wire leads 52, 54 interconnected with and extending from bipolar electrodes 48, 50 may be insert molded along with carrier member 22 such that wire leads 52, 54 are encapsulated into the material of carrier 22 while the bipolar electrodes 48, 50 are molded into the material so as to protrude outwardly from the outer surface of the carrier member 22. *Id.* at col. 6, ll. 21 – 28; *see* Figs. 3 and 4A. Since the bipolar electrodes 48, 50 protrude outwardly of the carrier member 22, it is respectfully submitted that bipolar electrodes 48, 50 are not covered by any portion of the carrier member 22. At most, only the wire leads 52, 54 would be covered by the material of the carrier member 22.

In another embodiment, Atlee describes a pair of ring-type electrodes 90 engaged with an outer wall of a carrier member 88 within shallow recesses formed in the carrier member 88. *Id.* at col. 8, ll. 9 – 12; *see* Figs. 10 – 11. Wire leads 92 interconnected with ring-type electrodes 90 may be either received within a passage 94 of the carrier member or insert molded with the carrier member 88. *Id.* at col. 8, ll. 12 – 19. Even when the ring-type electrodes 90 and the wire

leads 92 are insert molded with the carrier member 88, however, only the wire leads 92 are taught as being encapsulated within the material of the carrier member 88. *Id.* Thus, it is respectfully submitted that Atlee does not show or suggest that any portion of the carrier member 88 covers the ring-type electrodes 90.

In a further embodiment, Atlee describes a patch-type electrode array 98 mounted on an outer surface of a carrier member 96 and patch-type foil electrodes 98' mounted to an outer surface of carrier member 96'. *Id.* at col. 8, ll. 30 – 39; *see* Figs. 12A and 12B. It is respectfully submitted that patch-type electrode array 98 and 98' are only described as being mounted on the carrier members 96 and 96'. Thus, it is respectfully submitted that neither patch-type electrode arrays 98 and 98' are covered by any portion of the members 96, 96'.

Therefore, it is respectfully submitted that neither Freedman nor Atlee, either alone or in combination, show or suggest “*the sheath including an electrode that is embedded in the sheath so that the electrode is covered by a portion of the sheath,*” as recited in claim 1.

It is also respectfully submitted that Melnikoff does not cure the deficiency of Friedman, as discussed above in regard to claim 1. Melnikoff does not show or suggest a sheath or any other element covering any portion of a probe, let alone a sheath including electrodes embedded therein. Specifically, Melnikoff discloses an electrode 17 comprising an electrode dome 50 arranged on a unitary base 52, which are integrally formed. *Melnikoff*, col. 6, ll. 11-16. The electrode 17 is attached to a tube-like probe via connectors 55a and 55b, threaded sections 57a, 57b, adhesives, moldings, or snap fitting connectors. *Id.* at col. 7, ll. 40 - 42 and 53 – 63; *see* Figs. 2 and 7. It is respectfully submitted that Melnikoff specifically teaches that the electrode 17 is directly connected to the tube-like probe. Melnikoff does not teach a sheath covering any portion of the probe and thus does not teach a sheath including an electrode embedded therein so that a portion of the sheath covers the electrode 17. Furthermore, it is respectfully submitted that all of the connections described by Melnikoff, between the electrode 17 and the probe, are such that no portion of probe covers the electrode 17.

Thus, it is respectfully submitted that either Friedman nor Melnikoff, either alone or in combination, show or suggest a “*sheath including an electrode that is embedded in the sheath so that the electrode is covered by a portion of the sheath,*” as recited in claim 1.

It is respectfully submitted that Van Venrooij does not cure the deficiency of Friedman, as discussed above in regard to claim 1. Van Venrooij an insulating member that exposes portions of one or more electrodes carried by a brain stimulation lead. Van Venrooij does not show or suggest that the insulating member covering the stimulation lead includes electrodes embedded therein. Specifically, Van Venrooij describes a directional brain stimulation lead assembly for implantation in the brain including a lead body 20 with electrodes 24 formed therealong, about an exterior wall of the lead body. *Van Venrooij*, col. 5, ll. 44 – 48 and col. 6, ll. 1 – 3. Van Venrooij further describes an insulating member 10 including a substantially tubular body 12 with a window 16 such that when the insulating member 10 is placed over the lead body 12, only portions of the electrodes 24 are exposed, as desired. *Id.* at col. 5, ll. 11 – 17. The Examiner cites to portions of Van Venrooij to show embedded electrodes. *10/24/08 Office Action*, p. 5. However, it is respectfully submitted that in each of the instances cited by the Examiner, Van Venrooij teaches that the electrode 24 may be embedded in the lead body 20, rather than in the insulating member 10. *See Id.* at col. 5, ll. 49 – 52. Indeed, Van Venrooij teaches that specifically shaped electrodes 17 could be embedded in the lead body 20 such that the windowed insulating member 10 would be unnecessary. *Id.* at col. 15, ll. 38 – 41. Thus, it is respectfully submitted that Van Venrooij does not show or suggest that the insulating member 10 includes electrodes 24 embedded therein such that the electrodes 24 are covered by any portion of insulating member 10.

Thus, it is respectfully submitted that neither Friedman nor Van Venrooij, either alone or in combination, show or suggest “*the sheath including an electrode that is embedded in the sheath so that the electrode is covered by a portion of the sheath,*” as recited in claim 1.

Accordingly, it is respectfully submitted that claim 1 is not rendered obvious by Friedman alone or by Friedman in view of Atlee, Melnikoff or Van Venrooij and that the

§102(e) and § 103(a) rejections of this claim should be withdrawn. Because claims 2 - 5, 7, 8, 10, 12 – 13 and 24 – 26 depend from and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Similarly, claim 14 recites a cardioversion mechanism comprising “a flexible sheath sized to be received one of permanently and removably over a transesophageal echocardiography probe, *the flexible sheath including an electrode assembly that is embedded in the sheath so that the electrode assembly is covered by a portion of the sheath*, wherein, when the sheath is received by the echocardiography probe, electrodes of the electrode assembly are located at a predetermined location with respect to the echocardiography probe, the electrode assembly being coupled to a power source for supplying a cardioversion current to a heart when the echocardiography probe is in an operative position within an esophagus of a patient.”

For at least the same reason as discussed above in regard to claim 1, it is respectfully submitted that claim 14 is neither anticipated by Friedman nor rendered obvious by Friedman in view of Atlee, Melnikoff or Venrooij and that the rejections to this claim should be withdrawn. Because claims 15, 17-19 and newly added claim 27 depend from and, therefore, include the limitations of claim 14, it is respectfully submitted that these claims are also allowable.

Claim 20 recites a method of treating a heart of a patient, comprising the steps of “inserting into the patient’s esophagus a device comprising a flexible probe having an echocardiography transducer coupled to a distal end thereof and a flexible sheath sized to be received one of permanently and removably over the probe, *the sheath including at least one cardioversion electrode that is embedded in the sheath so that the electrode is covered by a portion of the sheath*” and “performing an echocardiography to analyze a condition of the heart” along with “applying electric current to the at least one electrode to supply a cardioversion current to the heart when the echocardiography does not contraindicate cardioversion.”

For at least the same reason as discussed above in regard to claims 1 and claim 14, it is respectfully submitted that claim 20 is neither anticipated by Friedman nor rendered obvious by

Friedman in view of Atlee, Melnikoff or Venrooij and that the rejections to this claim should be withdrawn. Because claims 21-23 depend from and, therefore, include the limitations of claim 20, it is respectfully submitted that these claims are also allowable.

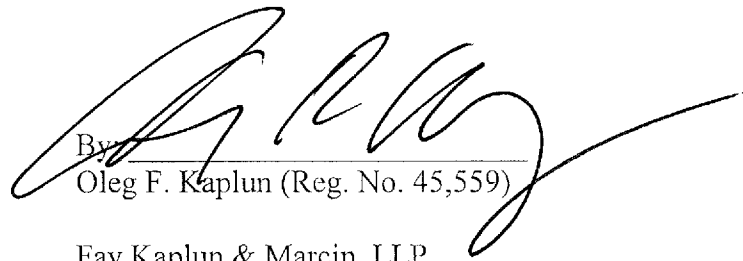
Claim 11 stands rejected under 35 U.S.C. § 103(a) as obvious over Friedman or, in the alternative, as unpatentable over Friedman in view of Shaddock. *10/28/08 Office Action*, p. 11. As discussed above, Friedman does not disclose or suggest a “*sheath including an electrode that is embedded in the sheath so that the electrode is covered by a portion of the sheath,*” as recited in claim 1, from which claim 11 depends. Accordingly, it is respectfully submitted that claim 11 is allowable as being dependent on an allowable base claim and that the Examiner should withdraw the 35 U.S.C. § 103(a) rejection of claim 11.

CONCLUSION

In light of the foregoing, Applicant respectfully submits that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated: March 24, 2009


By _____
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, New York 10038
Tel: (212) 212-619-6000
Fax: (212) 619-0276